

### Remarks

Claims 1-12, 16-19, 23 and 25-37 are pending in the application and subject to restriction.

Claims 36 and 37 are new. Support for the new claims can be found on page 14 lines 21-24, which states that the pharmaceutical formulation may be a freeze-dried matrix, with further discussion of freeze-dried formulations on page 17 lines 1-11 and, page 20 lines 27-32 and, with specific examples of freeze-dried matrix provided on page 27 lines 6-18. As noted on page 11 line 5-6, and as the Examiner will be aware, the terms "freeze-drying" and "lyophilization" are interchangeable.

The Detailed Action alleges that the claims of the application do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they allegedly lack the same or corresponding special technical feature. The lack of special technical features allegedly arises from US Pat. 4,780,149, which is alleged to teach  $\beta$ -limit dextrin containing starch hyrosylates via food and pharmaceutical products.

The Detailed Action further alleges that the claims are directed to more than one species of generic invention:

In claim 1: the bioadhesive pharmaceutical formulation as (i) a buccal-melt product, (ii) an aerosol powder, or a (iii) a thin film;

In claim 17: the nutritional product as (i) an energy drink or (ii) a confectionary product.

### Election

Applicants elect the claims of Group I, *i.e.*, claims 1-12, 16, 23 and 25, drawn to a bioadhesive pharmaceutical formulation comprising  $\beta$ -limit dextrin. Applicants further elect the species (i) buccal-melt product. The elections are made with traverse, for the reasons described below.

Claims readable on the elected species

The claims readable upon the buccal-melt species are as follows: 1-5, 7-12, 16, 23 and 25, *i.e.*, all claims of Group I with the exception of claim 6. Although the thin film embodiment of claim 7 was alleged to be a separate species by the Examiner, buccal-melt products may be in the form of a thin film and thus claim 7 is readable upon the elected species.

Newly added claim 36, which is believed to be properly grouped in Group I, also reads on the elected species of buccal melt.

As indicated below, request the rejoinder of Group III with the elected group, Group I. In furtherance of rejoinder, applicants state that the claims of Group III, comprising claims 26-29, would also read on the elected species of buccal melt. New claim 37, which would be grouped in Group III, is also believed to read on the elected species, buccal melt.

Travers of lack of unity objection as it relates to Groups I and III

Reconsideration and withdraw of the lack of unity objection is requested, as it relates to the separation of claims of Groups I and III. Rejoinder of the claims of Group III with the claims of elected Group I is requested.

The claims of Groups I and III are linked by the "special technical feature" that the formulation as claimed in the claims of Group I and as used in the method of claim 26 each comprise an active agent and a muco-adhesive carrier for the active agent, the muco-adhesive carrier comprising a  $\beta$ -limit dextrin. Although US Pat. 4780149 makes a passing reference to the use of  $\beta$ -limit dextrin in pharmaceutical products (see column 3 line 26-29), it provides no suggestion whatsoever of the use of  $\beta$ -limit dextrin as a muco-adhesive carrier in a bioadhesive type formulation. Indeed, this was acknowledged in the International Preliminary Examination Report in relation to the PCT application of which the present application is the US national stage. See the International Preliminary Examination Report, Separate Sheet, "Re Item V", attached. The advantages of using  $\beta$ -limit dextrins as a muco-adhesive carrier for delivery of active agents is not suggested in any way by the prior art.

It is believed that it is implicit that the formulation of the method of claim 26 is a bioadhesive formulation, as it comprises  $\beta$ -limit dextrin as a muco-adhesive carrier. However, to

more particularly point out and define the relationship between the method of Group III and the product of Group I, claim 26 has been amended to recite explicitly that the formulation is a bioadhesive formulation. Support for this amendment can be found from the application as filed, See for example page 13 lines 14-17.

#### Traverse of requirement for election of species

With regards to the requirement for election of species between buccal-melt type products, aerosol powders and thin films, each of these species share the special technical feature of claim 1, *i.e.*, the presence of  $\beta$ -limit dextrin as a muco-adhesive carrier for an active agent, which, as noted above, is not disclosed by the prior art. The species thus comply with PCT Rule 13.2 and should be considered as unified. As bioadhesive pharmaceutical formulations comprising  $\beta$ -limit dextrin as a muco-adhesive carrier, as claimed in claim 1, are novel and inventive over the prior art, under PCT Guidelines for assessment of unity of invention, no lack of unity can arise in respect of claims that depend on such an independent claim (see, for example PCT International Search and Preliminary Examination Guidelines Part 3 Chapter 10, paragraph 10.07).

The election of species requirement is further traversed to the extent that it separates buccal melts and thin films. A buccal melt can take the form of a thin film, as indicated above.

#### Conclusion

Reconsideration of the lack of unity objection is requested, to the extent traversed above.

Applicants reserve the right to seek rejoinder, as appropriate, on any ground provided by MPEP 804.

Respectfully submitted,

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## PATENT COOPERATION TREATY

PCT



## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D: 06 DEC 2004

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Applicant's or agent's file reference P31928A/GTO/BPU		<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/EP 03/08358	International filing date (day/month/year) 29.07.2003	Priority date (day/month/year) 02.08.2002	
International Patent Classification (IPC) or both national classification and IPC A23L2/00			
Applicant GLYCOLOGIC LIMITED			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input checked="" type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(II) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand  30.01.2004		Date of completion of this report  03.12.2004	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Uhl, M Telephone No. +49 89 2399-8654 	

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP 03/08358

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-36 as originally filed

**Claims, Numbers**

1-31 as originally filed

**Drawings, Sheets**

1/6-6/6 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP 03/08358

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees, the applicant has:

- ☐ restricted the claims.  
☒ paid additional fees.  
☐ paid additional fees under protest.  
☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.  
☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.  
☐ the parts relating to claims Nos. .

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	4-21
	No: Claims	1-3, 22-25, 28-31
Inventive step (IS)	Yes: Claims	4-21
	No: Claims	1-3, 22-27
Industrial applicability (IA)	Yes: Claims	1-27
	No: Claims	

2. Citations and explanations

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/EP 03/08358

**Re Item IV**

**Lack of unity of invention**

As already indicated in the international search report, the present application lacks unity of invention since the subject matter of both parts of the invention, namely that in claims 1-21 (pharmaceutical) and 22-31 (food) is not novel.

D1 US5482560, see in particular col.1, l.28-52, ex.1 and cl.11-13.

D2 US4780149, see in particular col.2, l.57-col.3, l.39, ex.1-3 and cl.1-3.

Therefore a common inventive concept is missing.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

US4780149 discloses the use of compositions comprising beta-limit dextrins in pharmaceuticals and food (see col.3, l.26-41, cl.1-3). US5482560 (col.1, l.28-52) the use of compositions comprising beta-limit dextrins obtained from waxy-starch in food and beverage products. Not disclosed are pharmaceutical formulations of the bioadhesive type. Subject matter of claims 1-3 is not novel over the prior art as far as pharmaceutical formulations are concerned and subject matter of claims 21-25 and 28-31 is not novel as far as food formulations are concerned. The condition of obtaining the dextrins from special starches as in claims 29-31 does not affect the question of novelty of the product itself (product by process claims).

The use of beta-limit dextrin as an energy source is not considered inventive as the use of beta-limit dextrin in a foodstuff means inevitable that it serves at least implicitly as energy source as it is a digestable substance.